REMARKS/ARGUMENTS

Claims 1 to 22 are currently pending in this application. Claims 23-36 have been withdrawn. Claims 1 to 4, 6 and 7 have been amended. No new matter has been introduced by the amendments set forth in this response.

Rejections Under 35 U.S.C. 112

The Examiner rejected claim 7 under 35 U.S.C. §112, 2nd paragraph as being indefinite. Applicant has amended the claim to clarify that the alloy must be free of at least one of Al, Ni or Be, in agreement with independent claim 1, thereby obviating this rejection.

Rejections Under 35 U.S.C. 103 Over Horton et al.

The Examiner rejected claims 1 to 22 under 35 U.S.C. §103(a) as being unpatentable over Horton et al. (U.S. Publication No. 2002/0162605) either alone, or in combination with Scheicher (U.S.P.N. 4,278,630), Lin (U.S.P.N. 5,797,443) or Oshida (U.S.P.N. 6,066,176). Applicant has amended independent claim 1, upon which claims 2 to 22 each rely, to include new limitations concerning the nature of the surface features formed thereon. Applicant will now address each of the references and rejections in light of these amended claims.

The Horton et al. Reference

The current invention is directed to a medical implant, which has engineered surface features formed using an amorphous metal that is free of at least one of Ni, Al and Be. More specifically, the current invention is directed to a dental prosthesis made with those bulk amorphous materials having specific physical properties, namely, those alloys that allow for the precision reproduction of highly intricate surface features. Specifically, Applicant has discovered that the ability to controllably engineer surface

features results in the production of substantially improved medical implants. The importance of these features is summarized by Applicant as follows:

> Unfortunately due to the small dimensions of acceptable morphological features, desired surface morphology cannot be readily produced onto current implant materials. Instead, mechanical and chemical methods, such as shot peening and acid etching, are used to fabricate surface morphology onto the implant material after the shaping and fabrication of the actual implant body. *Because of the statistical nature of these conventional only surface morphologies with relatively crude and random features and lacking consistency and precision both in the shape and the distribution of desired surface features have been produced. Indeed, the production of suitable surface morphologies can be said to be the result of statistical accidents rather than by design.*
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> Applicants have found that it is possible to form micro-structured surface morphologies by design using bulk-solidifying amorphous alloys. The unique amorphous atomic microstructure of these materials responds uniformly to the forming operations of micron and sub-micron scale making it possible to form features within the desirable morphological ranges. This is in distinct contrast to conventional metals and alloys, where the microstructure of the material is characterized by crystallites (individual grains typically with dimensions of few to several hundreds microns) each of which has different crystallographic orientation and, as such, responds non-uniformly to shaping and forming operations.
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> The micro-structured surface morphology according to the current invention can be produced in two alternative ways. In a first exemplary method, as outlined in FIG. 1, the surface morphology can be simultaneously formed during the fabrication of implant components by casting methods. In such an embodiment the mold surfaces used in the casting operation can be pre-configured to have the negative impression of the desired surface microstructure so that the bulk-solidifying amorphous alloy replicates such features upon casting. *The relatively low melting temperature of bulk-solidifying amorphous alloys and the lack of any first-order phase transformation during the solidification readily enables the replication of micron sized mold features during the casting of the implant components.* The solidification shrinkage is then dominated by the coefficient of thermal expansion rather than the volume difference between the solid and liquid state of the casting alloy. Accordingly, bulk

> amorphous alloys with low coefficients of thermal expansion (at temperatures from ambient to glass transition) are preferred. For example, Zr-base bulk solidifying amorphous alloys generally have a coefficient of thermal expansion of around 10^{-5} (m/m ° C.) providing low shrinkage rates. Such a process is highly desirable as several steps of post-finishing and surface preparation operations can be reduced or eliminated. (Specification, paragraphs 37 to 39, italics added for emphasis.)

In contrast, Horton et al. is directed broadly to the use of bulk solidifying amorphous alloys in any sort of medical tool, device, or implant. Nowhere do Horton et al. ever discuss the importance of engineered surface features, as claimed by Applicant. Indeed, Horton et al. only ever discuss three parameters as being of "importance" in producing their "medical devices": the hardness/toughness of the material, the elastic limit of the material, and the magnetic or imaging properties of the materials. (See, e.g., Horton et al., paragraphs 30, 34, 36, 46, 47 and 48.) Applicant can find no discussion or teaching anywhere in the Horton et al. reference that even suggests that the implant should be "precision engineered", as required by the claims of the instant invention. Moreover, where Horton et al. do discuss an important property of the underlying amorphous material it is only in the context of "matching" the elastic limit of the implant to the attached bone, not in maximizing the elastic limit to ensure that surface features may be more precisely engineered. (See, Horton et al., paragraph 36.)

Nor are the differences between the implants described by Horton et al., and those taught by the current invention surprising. As explicitly set forth in the amended claims, the current invention is directed to a "medical implant" having "precision engineered features" that are uniform on a very small size scale. As discussed by Applicant, such a prosthesis necessarily will be comprised of innumerable fine features. Moreover, as further described by the instant application it is essential to be able to accurately form these features in the implant to ensure good function. (Specification, paragraph 36.) In contrast, the only medical appliances taught by Horton et al. are

standard pieces such as, for example, plates, screws, pins, joints, clips, etc. (See, e.g., Horton et al., Table 2 and paragraph 36.) Nowhere do Horton et al. ever describe or even suggest the use of these materials to "form" the fine engineered surface features, and as such the specific technical challenges presented by such an application of these amorphous materials is simply never addressed or even considered by the authors.

In short, while Horton et al. describe a set of properties (hardness, toughness, and elastic limit) that are important to the proper practice of Applicant's invention, these properties are not *sufficient* to fully practice Applicant's invention. In addition, it is necessary to understand that the success or failure of the implant will rely on the shape and surface properties of the implant, and how one uses the unique properties of the amorphous materials to obtain those engineered shapes/surfaces. Accordingly, Applicant would respectfully submit that one of ordinary skill in the art, having read the entirety of the Horton et al. reference, would not have had the requisite knowledge to form the implants in accordance with the instant application.

The Scheicher Reference

Nor does the Scheicher reference address the fundamental deficiencies of the Horton et al. reference. The Scheicher reference is directed to ceramic materials having pores formed over a very gross size scale. For example, in the only discussion on the formation of pores in Scheicher the author writes:

> For the production of porous ceramic bodies, fibers in pieces of about 0.5-about 3 mm are particularly suitable. An adequately uniform distribution of the fibers in the base substances is generally sufficient to ensure that the ceramics manufactured from the substances have the desired rigidity. This applies especially for the production of porous ceramic bodies having surfaces not prone to rejection by the tissues and which enable adherence and ingrowth of bone tissue. These porous bodies contain a large number of vesicular cavities merging partly into one another like a sponge. The pores vary in diameter from the smallest pore of diameter less than 1 μm to pores with a diameter of over 500 μm, whereby in one piece of ceramic, pores of different sizes are evident. Pores of diameter from about 10 μm to about 400 μm are preferred. The average value of the pore diameter

> should be approximately 100-200 µm, whilst the quantity of pores having a diameter larger than 300 µm should not account for more than 10%, preferably 5%. In the porous bodies the pores take up a volume of about 10% to about 90% with respect to the total volume. Proportions of pores from about 20 Vol.% to about 30 Vol.% are especially suited for use as adhering layer for the ingrowth of tissue. (Scheicher, col. 2, lines 40 to 63.)

In short, Scheicher teaches a method of forming a randomly interconnecting porous structure, not a precision engineered and substantially uniform structure as claimed and set forth in the instant application. The reason for this difference is quite clear. Scheicher uses a material made of ceramic intermixed randomly with reinforcing fibers. (See, Scheicher reference throughout.) The result is that the pores formed are formed randomly, in the language of the instant application "statistically". There is no discussion or even suggestion of forming precision engineered and substantially uniform surface features on the size scale of µm's as claimed in the instant application. It should be noted again that one of the principal advantages recited for the use of amorphous materials in the instant application is the ability to replace such "statistical" methods of forming surface features with the ability to controllably "engineer" such features. For example, Applicant writes in relevant part:

> Because of the statistical nature of these conventional [techniques] only surface morphologies with relatively crude and random features and lacking consistency and precision both in the shape and the distribution of desired surface features have been produced. Indeed, the production of suitable surface morphologies can be said to be the result of statistical accidents rather than by design. (Specification, paragraph 37.)

This fact is certainly borne out by the Scheicher reference, which teaches that the pores will range from 10 to 400 µm with an "average" of between 100 to 200 µm, and that has 5 to 10% of features above 300 µm. Effectively, Scheicher are describing a "bell-curve" of differently dimensioned surface features, which is precisely the type of "statistical" surface morphology the claims of the instant application aim to avoid.

Accordingly, Applicant would submit that one of ordinary skill in the art, having read the entirety of the Horton et al. and Scheicher references, would also not have had the requisite knowledge to form the implants in accordance with the instant application.

The Lin et al. and Oshida References

As discussed above, Applicants do not believe the teachings provided by the Horton et al. or the Scheicher reference in any way render unpatentable the claims of the current application. Nor do either the Lin et al. or the Oshida references address the fundamental deficiencies of the Horton et al. and Scheicher references, namely that neither Horton et al. nor Scheicher ever teach, disclose or even suggest that the medical implants should have surface features engineered to be substantially uniform on a μm length scale.

Specifically, as indicated by the Examiner the Lin et al. publication is directed to novel amorphous alloy compositions, not to medical implants, and while Oshida does teach dental implants, the author is principally interested in coatings for said implants. As such, neither of these references ever provides any discussion concerning engineering surface features as claimed in the instant application. Accordingly Applicants would again respectfully submit that one of ordinary skill in the art, having read the entirety of the cited references and their combined teachings would have had no reason to form the implants taught by the instant application. In light of this deficiency, Applicants would submit that the claims of the instant application cannot be rendered obvious in view of the teachings of the Horton et al. in view of either Scheicher, Lin et al. or Oshida.

Conclusion

In view of the foregoing amendment and response, it is believed that the application is in condition for further examination. If any questions remain regarding

the allowability of the application, Applicant would appreciate if the Examiner would advise the undersigned by telephone.

Respectfully submitted,

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